

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

MDL NO. 1456

THIS DOCUMENT RELATES TO:
CLASS 1 J&J

CIVIL ACTION: 01-CV-12257-PBS
Judge Patti B. Saris

**CLASS 1 PLAINTIFFS' STATEMENT REGARDING POSITIONS TAKEN BY THE
DEPARTMENT OF JUSTICE REGARDING DR. HARTMAN'S 30% BENCHMARK**

Pursuant to the Court's request at the July 12, 2010 hearing on the J&J Defendants' Post-Remand Motions for Summary Judgment, the Class 1 Plaintiffs respectfully submit the following Statement regarding positions taken by the Department of Justice in the *Ven-A-Care* cases regarding Dr. Hartman's 30% benchmark.

I. THE DOJ'S POSITION

Based on their independent examination of the public record as well as inquiries to the DOJ and counsel for Ven-A-Care, Class Counsel are unaware of any litigation or settlement position taken by the Department of Justice regarding Dr. Hartman's 30% benchmark or the benchmark that should be applied to Medicare beneficiaries.

However, the DOJ's expert, Professor Mark G. Duggan, has calculated damages to the federal government by determining the difference between what the Government actually reimbursed for drugs provided to Medicare and Medicaid recipients versus what the Government would have paid had defendants reported more truthful prices. Professor Duggan determined what the Government would have paid by using defendants' transactional data to calculate 125%

of the average indirect price to the pharmacy class of trade. *See, e.g.*, Exp. Rpt. of Mark G. Duggan, Ph.D. submitted in *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs., Inc.*, Case No. 07-CV-11618-PBS, Dkt. No. 6626-3 (“Duggan Rpt.”) at 8-9.¹ Professor Duggan used this percentage based on his observations that (a) state Medicaid programs generally reimbursed at or below this level and (b) the price reporting services generally calculated AWP by applying a 20% to 25% mark-up from WAC. *See* Duggan Rpt. at 8 (“An examination of the public prices for Abbott products listed in the Complaint indicates that AWP for most of the period is typically 125% of the WAC.”). The DOJ has represented to this Court that it believes Professor Duggan’s 25% mark-up to be analogous to the 30 percent “speed limit” used by Dr. Hartman. *See* Dkt. No. 7073 at 5-6.

Therefore, while the DOJ has adopted the use of a “speed limit,” it has not taken any position regarding Dr. Hartman’s speed limit and, in fact, its expert has advocated a different speed limit than Dr. Hartman did.

II. THIS COURT SHOULD NOT CONSIDER MATERIAL NOT IN THE SUMMARY JUDGMENT RECORD

While the DOJ’s position submitted through Professor Duggan’s report indirectly supports the Class 1 Plaintiffs’ position that another factfinder could choose to adopt any speed limit supported by the evidence, this Court should not consider the positions taken by the DOJ because they are part of another proceeding and because the DOJ’s position is not part of the

¹ At the conclusion of the Class 2/Class 3 trial, Plaintiffs argued that this Court should apply a 25% benchmark to Remicade for Class 3, but this Court, though calling it “a close call,” rejected that approach. *See In re Pharm. Indus. Average Wholesale Price Litig.* (“AWP”), 491 F. Supp. 2d 20, 97 (D. Mass. 2007). Plaintiffs have therefore argued that a jury could decide to apply a benchmark other than Dr. Hartman’s 30% benchmark. As the First Circuit found: “[t]he court also found in its June 2007 post-trial order that the issue of what liability trigger to use for Remicade – an issue that turned on ascertaining the appropriate industry expectations – was a “close call,” . . . thus indicating that, had the court applied the Rule 56 standards, it might well have found there to exist a genuine issue of material fact.”); *In re AWP*, 582 F.3d 281, 286 (1st Cir. 2009) (internal citation omitted).

summary judgment record here. As the First Circuit held in *Hoffman v. Applicators Sales & Serv., Inc.*, 439 F.3d 9, 15 (1st Cir. 2006):

But Hoffman overlooks the crucial point that documents do not automatically become a part of the record simply because they are the products of discovery. *See Fed. R. Civ. P. 56(e)* (“sworn or certified copies of all papers or parts thereof referred to in an affidavit shall be attached thereto or served therewith”); *In re Citric Acid Litig.*, 191 F.3d 1090, 1101-02 (9th Cir. 1999) (“The document on which [the plaintiff] relies for its market share figures was not submitted as part of the summary judgment record, and thus we do not consider it.”). If a party wishes the court to consider matters disclosed during discovery, he must take appropriate steps to have them included in the record: merely citing to pages of discovery materials not of record does not suffice.

Neither Professor Duggan’s opinions nor the DOJ’s positions regarding those opinions are part of the record *in this case*. Cf. Electronic Order dated Nov. 21, 2006 (in denying Track 1 Defendants’ request to serve third-party trial subpoenas on government employees before Class 2/Class 3 trial, holding that “*Touhy* regulations are applicable *because the government is not a party . . .*”) (emphasis added). Indeed, on an analogous basis, when Track 2 Defendant Abbott Laboratories, Inc. (“Abbott”) sought in the First Circuit to introduce an “amicus brief” containing selected “government knowledge” depositions taken by the Track 2 Defendants that were never a part of the Track 1 trial record, the court rejected that attempt, holding that “[a]s Abbott Labs concedes, the evidence it seeks to submit here was not before the district court. Accordingly, it is not part of the district court record and therefore should not be considered by this court.” *See* Ex. A to Declaration of Steve W. Berman (July 9, 2008 Order of Court in Appeal Nos. 08-1055 and 08-1056).

Nor do the DOJ’s litigation positions constitute “adjudicative facts” about which this Court could take judicial notice under Fed. R. Evid. 201. *See Uncle Henry’s, Inc. v. Plaut Consulting, Inc.*, 240 F. Supp. 2d 63, 80 n.23 (D. Me. 2002) (sustaining objection to inclusion of

party's briefs on motion to transfer venue as "facts" to be considered on summary judgment), *aff'd*, 399 F.3d 33 (1st Cir. 2005). *Cf. United States v. Stroman*, 2006 U.S. Dist. LEXIS 870, at *24-25 (D. Me. June 9, 2006) ("I decline either to strike the Post-Hearing Notice, ignore the concealed-weapons statute or reopen the hearing. As the government points out, the Post-Hearing Notice is not a brief containing legal argument but simply a notice of a statutory citation – the type of information of which the court, in any event, must take judicial notice."), *aff'd*, 2006 U.S. Dist. LEXIS 6286 (D. Me. Feb. 14, 2006). J&J cannot use the DOJ's arguments in its case to replace evidence obtained in this case about government knowledge. *See Guzman-Ruiz v. Hernandez-Colon*, 406 F.3d 31, 36 (1st Cir. 2005) (denying request to take judicial notice of order in related wrongful termination case because "[n]ot only do pleadings, parties, issues, and facts differ in different cases, but plaintiffs cannot sidestep their neglect to offer evidence in this case by asking the court to rule on the basis of the record in another case.").

J&J has premised both of its post-remand summary judgment motions on the position that the record during the Class 2/Class 3 trial is sufficient to enter judgment in its favor. *See, e.g.*, Dkt. No. 6668 at 5 ("[t]his Court has already heard all of the evidence and made all of the fact findings needed in order to enter summary judgment in favor of the J&J Defendants with respect to Class 1 residents of Massachusetts"); Dkt. No. 6672 at 18 ("There is no possibility or occasion for a jury to decide the facts differently than they have already been decided by the Court."). That record established that, regardless of the Government's knowledge, it could not have acted to prevent the harm caused by Defendants' conduct. *See In re AWP*, 491 F. Supp. 2d at 31 ("neither the third party payors nor the government could move quickly or effectively to fix the problem"); *id.* at 94-95 ("Moreover, defendants knew that neither the government nor the TPPs could do much to change the AWP reimbursement benchmark because they were locked

into the nationwide reimbursement scheme established by statute or contract.”). Therefore, government knowledge is not the relevant question; the government’s ability to act on that knowledge is. J&J cannot go beyond the record *in this case* to argue otherwise.

III. THIS COURT SHOULD NOT APPLY ANY “GOVERNMENT BENCHMARK” TO CLASS 1

Regardless of the benchmark believed to apply to the Government, that benchmark should not be applied to Class 1. In remanding this matter back to this Court, the First Circuit pointed out that this Court’s acceptance of the 30% benchmark for Classes 2 and 3 was based on *factual* underpinnings about what those Classes knew. *See In re AWP*, 582 F.3d 231, 237 (1st Cir. 2009) (“Its [J&J’s] characterization of the district court’s decision to adopt the 30% potential liability trigger as ‘legal’ (and therefore outside the purview of the jury) fails to account for the fact that the creation of the 30% trigger depended on factual findings relating to the relevant expectations as to the size of spreads.”). The First Circuit’s conclusion precludes this Court from taking the analysis of those factual underpinnings and the determination of damages from the jury. *See Incase, Inc. v. Timex Corp.*, 488 F.3d 46, 57 (1st Cir. 2007) (“Although whether a particular set of acts, in their factual setting, is unfair or deceptive is a question of fact, the boundaries of what may qualify for consideration as a Chapter 93A violation is a question of law.”) (*cited in In re AWP*, 582 F.3d at 156, 163).

For states that do not require a jury – California, Illinois, Massachusetts, Nebraska, New Hampshire and North Carolina², this Court should only consider the knowledge of Class 1. The parties agree that Class 1 knew nothing about J&J’s conduct and Dr. Hartman himself testified

² North Carolina gives the role of determining unfair conduct to the Court, but the role of determining damages to the jury. Were this Court to apply its bench trial ruling, which applied Dr. Hartman’s 30% benchmark as the most important of three factors it considered in determining whether Defendants’ conduct was “unfair” (*In re AWP*, 491 F. Supp. 2d 20, 101-02 (D. Mass. 2007)), this would effectively take the determination of damages from the jury.

that his benchmark did not apply to consumers. *See* Ex. 22 to Dkt. No. 6834 [Trial Tr. Day 9 (11/21/06) at 42:7-10] (“Q: Dr. Hartman, your 30 percent expectation yardstick doesn’t relate to consumers, does it? It relates to third-party payors, correct? A: That’s correct.”). Thus, because Class 1 had no knowledge of the J&J Defendants’ conduct, the only way that this Court can apply a government benchmark to Class 1 is to determine as a matter of law that the alleged knowledge of the Government may be in some way attributed to Class 1. No such basis exists.

First, in the context of Class 2, this Court already rejected the argument that that Government’s knowledge could be “imputed.” *See In re AWP*, 252 F.R.D. 83, 97 n.32 (D. Mass. 2008) (“Defendants make a strained argument that Medicare’s knowledge of mega-spreads should be imputed to the TPPs in the Medigap Class. However, Medicare was not the agent of the TPPs that had contracts to reimburse beneficiaries, and Medicare did not approve set or drug prices.”). Second, J&J’s “learned intermediary” analysis fails because, unlike a physician, the Government had no power to protect Medicare beneficiaries and there is no other legal relationship between the Government and Medicare beneficiaries – agency, fiduciary or otherwise – that would justify such an imputation.³

Finally, even if this Court found a legal mechanism to “impute” knowledge, there is no basis to do so here because this Court already found that the Government could not have acted in response to any such “knowledge” and because there are genuine issues of material fact regarding J&J’s concealments of its prices and conduct from the Government.

³ J&J argues knowledge should be imputed just as TPP knowledge was imputed to Class 3 consumers (*In re AWP*, 252 F.R.D. at 97), but in that citation the Court was relying on the Restatement (Third) of Agency § 5.03 – which says that the knowledge of an agent can be imputed to a principal. There is no principal/agent relationship between the Government and Class 1.

DATED: July 19, 2010

Respectfully submitted,

HAGENS BERMAN SOBOL SHAPIRO LLP

By: /s/ Steve W. Berman
Thomas M. Sobol (BBO#471770)
Edward Notargiacomo (BBO#567636)
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Telephone: (617) 482-3700
Facsimile: (617) 482-3003

Liaison Counsel

Steve W. Berman
Sean R. Matt
1918 8th Avenue, Suite 3300
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594

Jennifer Fountain Connolly
1629 K St. NW, Suite 300
Washington, D.C. 20006
Telephone: (202) 355-6435
Facsimile: (202) 355-6455

WEXLER WALLACE LLP
Kenneth A. Wexler
55 W. Monroe Street, Suite 3300
Chicago, IL 60603
Telephone: (312) 346-2222
Facsimile: (312) 346-0022

SPECTOR, ROSEMAN, KODROFF & WILLIS P.C.
Jeffrey L. Kodroff
John A. Macorella
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Telephone: (215) 496-0300
Facsimile: (215) 496-6611

EDELSON & ASSOCIATES, LLC
Marc H. Edelson
45 West Court Street
Doylestown, PA 18901
Telephone: (215) 230-8043
Facsimile: (215) 230-8735

Co-Lead Class Counsel

CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

In re Pharmaceutical Industry Average Wholesale Price Litigation
Master Case No. 01-cv-12257, MDL 1456

I, Steve W. Berman, hereby certify that I am one of the attorneys for the Class and that, on July 19, 2010, I caused a copy of **CLASS 1 PLAINTIFFS' STATEMENT REGARDING POSITIONS TAKEN BY THE DEPARTMENT OF JUSTICE REGARDING DR. HARTMAN'S 30% BENCHMARK** to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

HAGENS BERMAN SOBOL SHAPIRO LLP

/s/ Steve W. Berman
Steve W. Berman
1918 Eighth Avenue, Suite 3300
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594